

**MAY 19 2004**

**510 (k) SUMMARY  
SUMMARY OF SAFETY AND EFFECTIVENESS**

**FOR**

**BAUSCH & LOMB® MULTI-PURPOSE SOLUTION NRC07**

**1. Submitter Information**

Bausch & Lomb Incorporated  
1400 North Goodman Street  
Rochester, New York 14609

Contact Person: Glenn A. Davies, O.D.  
Director, Regulatory Affairs

Telephone Number: 585-338-8172

**2. Device Name**

Classification Name: Soft (hydrophilic) Contact Lens Care Solution

Proprietary Name: Bausch & Lomb Multi-Purpose Solution NRC07

**3. Predicate Devices**

Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution, Alcon Opti-Free Express Multi-Purpose Disinfecting Solution, AMO Complete MoisturePLUS Multi-Purpose Solution and Bausch & Lomb Multi-Purpose Solution NRC03 have been selected as the predicate devices for Bausch & Lomb Multi-Purpose Solution NRC07.

**4. Description of the Device**

Bausch & Lomb Multi-Purpose Solution NRC07 is a sterile isotonic solution containing boric acid, sodium chloride, sodium phosphate, Hydranate® (hydroxyalkylphosphonate), poloxamer 407, polyquaternium-10, poloxamine 1107, purified water and preserved with Alexidine dihydrochloride (0.00045%). The product is indicated for use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

The sterile solution is contained in a plastic bottle with a tamper evident seal and is labeled with a lot number and expiration date.

**5. Indications for Use**

Bausch & Lomb Multi-Purpose Solution NRC07 is indicated for use in the daily cleaning, removal of protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

**6. Description of Safety and Substantial Equivalence**

A series of preclinical and clinical studies were completed on this product. The following studies have been completed:

Toxicology

A series of cytotoxicity and eye irritation studies of the Bausch & Lomb Multi-Purpose Solution NRC07 and lenses cycled in the solution were undertaken. In these studies, there was no evidence of toxicity.

Lens Compatibility

Lens compatibility studies were undertaken after cycling lenses in the solution. The results indicated that lenses were compatible with the solution.

Microbiology

Disinfection efficacy was evaluated according to the FDA Guidance document as well as modifications to established procedures. The results indicate satisfactory levels of disinfection efficacy. Preservative Efficacy Testing with Rechallenge was evaluated. All results were satisfactory.

Stability

Stability testing is ongoing. All results are satisfactory.

Cleaning Efficacy

The cleaning efficacy of the solution has been evaluated through the determination of the Critical Micelle Concentration. The surfactant concentrations are well above the CMC for the individual surfactants.

The ability of the solution to prevent the deposition of protein has been established by the evaluation of protein present on the lens following solution usage in a no rub with a rinse regimen with a four (4) hour disinfection time. Protein deposition was significantly prevented as measured by Image Analysis.

The efficacy of the product to remove protein deposits measured by chemical analysis was evaluated with protein deposited lenses. For Group 4 lenses, the amount of lysozyme remaining was found to be statistically less after treatment with the Multi-Purpose NRC07 Test regimen when compared to the Control.

#### Cleanliness Analysis of Clinical Lenses

The evaluation of lens cleanliness by practitioners during a 3-month clinical investigation demonstrated that the overall occurrence of deposits was less with Bausch & Lomb Multi-Purpose Solution NRC07. In addition, the degree and percent coverage of deposits was significantly less with Multi-Purpose Solution NRC07. Following the clinical evaluation, lenses were returned for image analysis. The analysis of lens cleanliness from both Bausch & Lomb Multi-Purpose Solution NRC07 and Control regimens indicates that the mean density and percent coverage is more favorable for Multi-Purpose Solution NRC07 when evaluated by Image Analysis.

#### Lens Wettability

Lens wettability over time has been assessed by measurement of contact angle and continued presence of wetting agents over time for both Bausch & Lomb Multi-Purpose Solution NRC07 and Control solutions. The results indicated statistical significance for longer wetting ability over the Controls.

#### Clinical Study

A 3-month controlled, randomized study of daily wear contact lens use designed to evaluate the safety and efficacy of the Bausch & Lomb Multi-Purpose Solution NRC07 was completed. Safety and efficacy of the solution was demonstrated when compared to the Control.

The evaluation of lens cleanliness by practitioners demonstrated that the overall occurrence of deposits was less with Multi-Purpose Solution NRC07. In addition, the degree and percent coverage of deposits was significantly less with Multi-Purpose Solution NRC07.

Among the general patient population entering the study, the results demonstrated that comfort was sustained over the course of the 3-month study for patients that used Multi-Purpose Solution NRC07. Among patients entering the study with a subject assessment of dryness associated with contact lens wear, the results demonstrated that use of Multi-Purpose Solution NRC07 provided statistically significantly better outcomes for subjective dryness scores when compared to the Control.

In addition, the solution may help provide improved comfort for contact lens wearers who experience symptoms related to dryness during lens wear.

**510(k) Premarket Notification**  
**Bausch & Lomb® Multi-Purpose Solution NRC07**

**Substantial Equivalence**

Bausch & Lomb Multi-Purpose Solution NRC07 is substantially equivalent to Bausch & Lomb Multi-Purpose Solution NRC03, Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution, Opti-Free Express Multi-Purpose Disinfecting Solution and Complete MoisturePLUS Multi-Purpose Solution.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAY 19 2004**

Bausch & Lomb  
c/o Glenn A. Davies, O.D.  
1400 N. Goodman St.  
Rochester, NY 14609

Re: K033854  
Bausch & Lomb Multi-Purpose Solution NRC07  
Regulation Number: 21 CFR 886.5928  
Regulation Name: Soft (hydrophilic) Contact Lens Care Products  
Regulatory Class: Class II  
Product Code: LPN  
Dated: April 7, 2004  
Received: April 8, 2004

Dear Dr. Davies:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink that reads "A. Ralph Rosenthal". The signature is fluid and cursive, with the first name "A." and last name "Rosenthal" clearly legible.

A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K033854

Device Name: Bausch & Lomb Multi-Purpose Solution NRC07

### Indications for Use:

Bausch & Lomb Multi-Purpose Solution NRC07 is indicated for use in the daily cleaning, removal of protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter-Use X *JS*  
(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Myra Smith*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number K033854